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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/536,875	12/01/2006	Kristen Briggs	P0850.70005US01	6405

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WOLF GREENFIELD & SACKS, P.C.
600 ATLANTIC AVENUE
BOSTON, MA 02210-2206

EXAMINER	
WEN, SHARON X	

ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
05/25/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/536,875	BRIGGS ET AL.	
	Examiner	Art Unit	
	SHARON WEN	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02/18/2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31,38-53,67-69,75 and 76* is/are pending in the application.

4a) Of the above claim(s) *10,19-23,30,31,47 and 67-69* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,11-18,24-29,38-46,48-53,75 and 76* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/04/2007, 1/30/2008, 07/07/2008 and 10/09/2008*
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment, filed 02/18/2010, has been entered.

Claims 32-37, 54-66, 70-74 and 77 have been canceled.

Claims 1-31, 38-53, 67-69, 75-76 are pending.

Applicant's election without traverse of Group I and species anti-herpes simplex virus antibody and glycan species 3Man, 2GlcNAc, 1Xyl in the replies filed on 02/19/2009, 05/29/2009 and 02/18/2010 is acknowledged.

Claims 10, 19-23, 30-31, 47, 67-69 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Inventions/species, there being no allowable generic or linking claim.

Claims 1-9, 11-18, 24-29, 38-46, 48-53 and 75-76 are currently under examination as they read on a plant-produced immunoglobulin.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 12/04/2007, 1/30/2008, 07/07/2008 and 10/09/2008 have been considered by the examiner.

Claim Rejections - 35 USC § 112 second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 recites the limitation "the hexose" and "the N-acetylhexose". However there is insufficient antecedent basis for these limitations in the claim which it depends from, claim 12, because Applicant has deleted these limitations from claim 12.

Claim Rejections - 35 USC § 112 first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9, 11-16, 18, 24-27, 29, 38-40, 42-43, 45-46, 48-53 and 75-76 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Although Applicant has elected species anti-herpes simplex virus antibody as the antigen-specific antibody, the present claims do not recite an antigen specificity for the claimed antibody. Therefore, the following grounds of rejection is set forth for an antibody without antigen-specificity.

Antibodies are glycoproteins that possess the ability to react in vitro and in vivo specifically and selectively with the antigenic determinants or epitopes eliciting their production or with an antigenic determinant closely related to the homologous antigen.

Antibodies are immunoglobulins that are formed in response to immunogens or that are screened for specificity an antigen / immunogen.

It has been well established in the art that the antigen binding specificity is critical to how the skilled artisan would employ antibodies in various modalities (e.g., affinity purification, detection or diagnostic assays, bioassays, treatment), including those consistent with the instant disclosure (see specification, including the Summary of the Invention).

However, the instant claims do not recite an antigen specificity for herpes simplex virus (HSV).

The specification provides insufficient direction or guidance regarding how to make and use antibodies *in the absence of an antigen specificity for HSV* and yet retain substantially the same binding specificity of the anti-HSV antibodies to used for treating HSV infection, which are enabling consistent with the disclosed utilities of the instant disclosure (see, e.g., paragraph [0252])

Given the well known polymorphism of antibodies, it would have been undue

experimentation to make and use the vast repertoire of antibodies encompassed by the claimed invention in the absence of binding specificity for HSV to enable the scope of the claimed antibodies encompassed by the claimed invention.

Without sufficient guidance and given the well known complexity and unpredictability of using antibodies with no particular antigen specificity as well the well known polymorphism of antibodies; it would be unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue to make and use the vast repertoire of antibodies broadly encompassed by the claimed invention in order to make and use the anti-HSV antibodies consistent with the instant disclosure.

Applicant is invited to amend the present claims by reciting the antigen-specificity, HSV.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9, 11-15, 18, 24-26, 29, 45-46 and 48-53 are rejected under 35 U.S.C. 102(b) as being anticipated by Elbers et al. (Plant Physiology, July 2001, 126:1314-1322, cited on IDS, see entire document).

Elbers et al. taught plant-produced immunoglobulins isolated from the plants that produced the immunoglobulin, wherein the immunoglobulins have at least one glycopeptide that lacks fucoses and wherein the glycan profile is the same or substantially the same as the structure in Figure 12 of the present application (see, e.g., page 1316, Composition of Complex N-Glycans; page 1317, Table 1, structure K; page 1320, Separation of IgG from Endogenous Glycoproteins of Tabacco Leaves). Given that the glycan profiled taught by Elbers are N-linked, the immunoglobulins comprising

the N-linked glycan would have an asparagine (Asn) residue in CH2 region because by definition, N-linked means the glycan is attached to the nitrogen of the Asn residues in the Asn-X-Ser or Asn-X-Thr motifs. Moreover, given that N-linked glycans are also found in mammalian produced antibodies, the glycan with fucose found in Elbers's plant-produced immunoglobulin would be found attached to the same or substantially the same amino acid fragment such as the Asn-X-Ser or Asn-X-Thr motifs as the immunoglobulins produced in mammalian cells.

Furthermore, the plant-produced immunoglobulins taught by Elbers are IgG which would have a heavy and light chain as these are inherent properties of antibodies (see, e.g., page 1319, right column, third paragraph). Moreover, the glycan profile on Elbers's immunoglobulin was determined using MALDI-TOF analysis of free-N-linked glycans enzymatically-released from the antibody by trypsin digest (see page 1320 right column, Isolation of N-Linked Glycans).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 14-17, 27-28, 38-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Elbers et al. (Plant Physiology, July 2001, 126:1314-1322, cited on IDS) in view of Mayfield et al. (US 2004/0014174).

The teaching by Elbers et al. has been discussed above.

Elbers et al. did not teach the antibody to be anti-herpes simplex virus antibody nor did Elbers et al. teach that the antibody is an IgA or a human antibody. However, it would have been obvious to one ordinary skill in the art to express an anti-HSV IgA antibody because Mayfield et al. taught expressing an anti-HSV monoclonal antibody in transgenic plants (see e.g., paragraph [0237]). Furthermore, Mayfield et al. taught

engineering and an IgA antibody (paragraph [0018]) and human antibodies (paragraph [0084]). Moreover, Mayfield et al. taught expressing antibody fragments such as scFv that would have lack a tailpiece in plants.

Upon reading the teaching by Elbers and Mayfield, one of ordinary skill in the art would have been motivated to express an anti-HSV IgA human antibody in transgenic plants because plants are cost-efficient and contamination-safe factories for the production of recombinant proteins (see Elbers et al., page 1314, last paragraph). One of ordinary skill would also have reasonable expectation of success to produce the anti-HSV antibody in plants because many monoclonal antibodies have been successfully produced in plants such as that taught by Mayfield and also see Elbers et al. (page 1314, last paragraph). Given that glycan profiles are crucial for biological activity, stability, solubility, immunogenicity and plasma clearance of many glycoproteins, one of ordinary skill in the art would have been reasonably expected to engineer antibodies that have various glycan profiles such as that taught by Elbers (see Table 1) to optimize the antibody for its usages.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHARON WEN whose telephone number is (571)270-3064. The examiner can normally be reached on Monday-Thursday, 8:30AM-6:00PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571)272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sharon Wen/
Examiner, Art Unit 1644
May 24, 2010